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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,648	02/05/2001	Toshiaki Takezawa	202785US0X	3290

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

10

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,648

Applicant(s)

TAKEZAWA ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 10-21, 24-26 and 30 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 9, 22, 23, 27-29 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

This office action is in response to an amendment filed 4/14/03, paper No. 9. Claims 1 and 2 have been amended. Claims 1- 31 are pending.

Response to Amendment

The substitute specification submitted filed 4/14/03, Paper No. 9 has been received. However, amendments to the specification do not put the specification in proper idiomatic English and therefore the substitute specification will not be entered.

Rejection of claims 2 and 11-21 under 35 U.S.C. 112, second paragraph, is withdrawn in light of amendment to claim 2 to clarify that the cells, tissue and organs are derived from animals.

Rejection of claims 1-4, 6-18, 22-25 and 27-31 under 35 U.S.C. 112, first paragraph, are withdrawn in light of amendment to claim 1. Specifically, the claim is amended to recite that the tissue can substitute a function of endometrial tissue.

Specification

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. The specification is of improper idiomatic English. Several passages are difficult to comprehend. For example, page 2, line 1-3 recites "... a late

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blastula stage wherein zona pellucida is denatured and disappeared, and the fertilized ovum at the stages from cleavage to blastula stage is transplanted in an uterus to obtain a baby." First, use of the term "disappeared" is incorrect, it would be remedial to substitute dissolved. It would be remedial to substitute "a" for "an" prior to uterus. Secondly, it is difficult to determine if the fertilized ovum can be transplanted any time during the stages of cleavage to blastula stage or if the transplantation occurs while the ovum is in the midst of these processes. As a second example, see page 3, line 6-8 which recites "In rabbits, a report exists which cultures endometrial epithelial cells in a matrigel, a reconstituted basement membrane, and thereafter to place a blastocyst just before implantation thereon for culturing." A report cannot culture endometrial epithelial cells and therefore it is unclear what actually cultures the cells and what places the blastocyst and where the blastocyst is placed thereon for culturing. Several such passages are found throughout the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8, 10, 11, 13, 17-19, 24-26 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Spaulding et al., US patent 6,001,643.

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Spaulding et al teach use of a hydrodynamic cell culture environment comprised of a tissue culture chamber for three-dimensional tissue growth (abstract and column 9, line 44-57).). As a general method, tissue is introduced into a roller bottle that is constructed of material suitable for cell and tissue culture i.e. polystyrene, nylon and the like (column 7, line 20-30). Cells are suspended in media in the chamber and as the cells aggregate, they form an autologous extracellular matrix upon which cells adhere, differentiate and become 3-dimensional tissue (column 14, line 61-column 15, line 1). Specifically for use in developing embryos, Spaulding et al teach co-culturing of a fertilized ovum of an animal with endometrial tissue in the chamber. Therefore, the carrier of Spaulding et al comprises a scaffold (endometrial tissue) for the cellular growth of a fertilized egg once it is implanted. Spaulding teaches that the endometrial tissue is co-cultured with the fertilized egg such that endometrial implantation constructs are formed that support endometrial maturation until it is transplanted into a recipient uterus (example 8, column 20, line 29-56

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 11-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 11-21 by dependency are vague for reciting cells, tissues, and organs derived from animals. It is unclear how closely related the derived cells, tissues or organs are to

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the original animals. It is also unclear what procedures were used to derive cited cells, tissue or organs from animals. The metes and bounds of the claimed subject matter are unclear. **This rejection is necessitated by amendment.**

Response to Arguments

Applicants traverse 35 U.S.C. 102(e) as being anticipated by Spaulding et al., US patent 6,001,643 rejection of 1-5, 8, 10, 11, 13, 17-19, 24-26 and 30. Applicant argues that the instant invention is fundamentally different from the present invention as Spaulding et al. do not disclose or suggest the use of a cell type incorporated three-dimensionally reconstructed tissue as means for inducing adhesion and three-dimensional growth of a fertilized ovum for co-culturing the fertilized ovum of an animal. Therefore, Spaulding et al. fail to anticipate the claimed invention.

The rejection of claims based upon 35 U.S.C. 102(e) stands as applicant teaches that the definition for a cell incorporated type three-dimensional reconstructed tissue" is "a scaffold for growing three-dimensional tissue derived from fertilized ovum" (Paper No. 6, page 9 further referring to the disclosure page 9, lines 19-21). Therefore, since Spaulding teaches a scaffold comprised of endometrial tissue for growing a three-dimensional fertilized ovum, it meets the limitations of the instantly claimed invention. Spaulding teaches use of endometrial tissue placed into a roller bottle, which becomes the carrier for co-culturing with the fertilized egg. Endometrial implantation constructs are formed that support endometrial maturation (example 8, column 20, line 29-56). These construct are designed for the adherence of the

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embryo for subsequent transfer to a "receptive uterus". According to Stedman's medical dictionary, implantation is defined as

1. Attachment of the fertilized ovum (blastocyst) to the endometrium, and its subsequent embedding in the compact layer, occurring 6 or 7 days after fertilization of the ovum in humans.

Therefore, Spaulding et al. anticipate the instant invention by providing a scaffold for the adherence and three-dimensional growth of a fertilized ovum.

Conclusion

Claims 1-5, 8, 10-21, 24-26 and 30 are rejected.

Claims 6, 7, 9, 22-23, 27-29 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3553.

Maria B Marvich, PhD
Examiner
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June 24, 2003


TERRY MCKELVEY
PRIMARY EXAMINER